

Express Mail Label No. EV 336 040 092 US

Attorney Docket No. 59150-8010

**REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated April 29, 2003 are respectfully requested. Applicant petitions the Commissioner for a 1-month extension of time. A separate petition accompanies this amendment.

**I. Amendments****A. In the Specification:**

The specification is amended in accordance with 37 C.F.R. §1.821 through 1.825 to add the Sequence Listing.

The specification and claims is amended in accordance with 37 C.F.R. §1.821(d) to add sequence identifiers preceded by SEQ ID NO.

The specification is further amended to correct Figure numbering.

**B. In the Claims:**

Claims 1, 13-16, 18, and 19 are amended to recite a native virus envelope. Support for this amendment can be found on page 2, lines 29-32.

Claims 2-12 and 20-21 are amended in accord with the Examiner's kind suggestion for proper format.

No new subject matter has been added by way of these amendments.

**II. Sequence Listing**

The Examiner objected to the specification for allegedly not complying with the requirements for patent applications containing nucleotide and/or amino acid sequence disclosures.

Applicants have amended to specification to include the Sequence Listing in compliance with 37 C.F.R. §1.821 through §1.825.

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### III. Drawings

The Examiner objected to the drawings based on the objections by the draftsperson. Applicants submit herewith corrected formal drawings.

### IV. Objections to the Claims

The Examiner objected to claim 2-12 and 20-21 for alleged informalities. Specifically, the Examiner objected to the phrase "A gene transfer vector according to claim" as allegedly improper format for a dependent claim.

Applicants have amended claims 2-12 and 20-21 in accord with the Examiner's kind suggestion.

### V. Rejection under 35 U.S.C. §112, first paragraph

Claims 1, 13-16, 18-19, and claims dependent therefrom were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1, 13-16, 18-19, and claims dependent therefrom, were further rejected under 35 U.S.C. §112, first paragraph, allegedly because the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected to make and use the invention commensurate in scope with the claims.

These rejections are respectfully traversed.

#### A. Written Description

Specifically, the Examiner asserts that the specification fails to specifically disclose a virus envelope membrane. Although the term "virus envelope membrane" is not specifically recited in the specification, the specification clearly recites a gene transfer vector comprising an exogenous gene encapsulated in a virus envelope (page 15, lines 11-14). It is well known to one of skill in the art that a virus envelope

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comprises a lipid bilayer membrane, and the terms "virus envelope" and "virus envelope membrane" are used interchangeably in the art.

However, to further prosecution, Applicants have amended claims 1, 13-16, 18, and 19 to recite a virus envelope as disclosed on page 15, line 14.

Accordingly, Applicants submit that these teachings in the specification show that Applicants had possession of the invention as presently claimed at the time of filing.

#### B. Enablement

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention without undue experimentation (e.g., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir., 1991).

Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples (*In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed Cir. 1993)).

The enablement requirement is met if the description enables any mode of making and using the claimed invention (*Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991).

With regard to how to make a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope membrane, Example 1 (pages 20-22) sets forth a specific example of the claimed invention. Specifically, Example 1 shows the preparation of a gene transfer vector by encapsulating the luciferase gene in an HVJ envelope employing freezing and thawing. Example 2 (pages 22-23) examines the gene transfer efficacy of the gene transfer vector prepared in Example 1.

Accordingly, Applicant submits that the specification would enable any person skilled in the art to which it pertains to make and use the claimed invention.

In light of the teaching in the specification and Applicant's amendments, Applicant submits that the present claims satisfy the requirements of §112, first paragraph and respectfully request that the rejections be withdrawn.

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**VI. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1, 13-16, 18-19, and claims dependent therefrom were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Specifically, the Examiner objected to the language "virus envelope membrane" allegedly as a relative term, which renders the claim indefinite.

As described above, one of skill in the art is well acquainted with the term "virus envelope membrane" as a virus envelope comprising a lipid bilayer membrane. However, to further prosecution, Applicants have amended claims 1, 13-16, 18, and 19 to recite a virus envelope as disclosed on page 15, line 14.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

**VII. Rejections under 35 U.S.C. §102**

Claims 18 and 31-33 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Hoon et al. (U.S. Patent No. 6,472,375).

Claims 1-9, 11-12, 16, 18, 20-22, and 30-33 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ramani et al. (*PNAS*, 95:11886-18890, 1998).

These rejections are respectfully traversed for the following reasons.

**A. The Invention**

The present invention relates to a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope (claim 1), as well as a method for preparing the gene transfer vector (claim 16), and a method for introducing a gene into animal tissue using the gene transfer vector (claim 18).

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**B. The Cited Art**

HOON ET AL. disclose a viral liposome composition comprising a liposome fused to an inactivated virus and comprising a nucleic acid, preferably DNA encoding a tumor-associated antigen.

RAMANI ET AL. disclose an engineered viral envelope using only the fusion glycoprotein for delivery of a reporter gene.

**C. Analysis**

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

**1. Rejection over Hoon et al.**

Hoon *et al.* fail to teach a method for introducing a gene into isolated animal tissue comprising preparing a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope. Hoon *et al.* teach the use of a viral liposome composition comprising a liposome fused to an inactivated virus.

**2. Rejection over Raimani et al.**

Raimani *et al.* fail to teach a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope. Raimani *et al.* further fail to teach a method of making a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope or using the vector to introducing a gene into animal tissue. Raimani *et al.* teach an engineered viral envelope using only the fusion glycoprotein.

As the standard for novelty has not been satisfied, withdrawal of the rejections under 35 U.S.C. §102 is respectfully requested.

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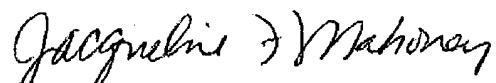
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**VIII. Conclusion**

In view of the foregoing, Applicant submits that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,



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Date: Aug. 29, 2003

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